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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,258	10/12/2001	Robert C. Corcoran	08446.0002	8853

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EXAMINER

THERKORN, ERNEST G

ART UNIT PAPER NUMBER

1723

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,258

Applicant(s)

CORCORAN, ROBERT C.

Examiner

Ernest G. Therkorn

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-140 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-81, 87-91, 93, 94, 99, 101, 103-109, 114-116, 121-123, and 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 82-86,92,95-98,100,102,110-113,117-120,124-127 and 129-140.

Claims 79, 80, 81, 87-91, 93-94, 99, 101, 103-109, 114-116, and 121-123 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support can be found for "without the addition of a reagent acting at the covalent bond." As such, the claims are considered to be drawn to new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 79, 80, 87-91, 93-94, 106-107, 114, and 121-122 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hyalarides (U.S. Patent No. 5,141,648). The claims are considered to read on Hyalarides (U.S. Patent No. 5,141,648). However, if a difference exists between the claims and Hyalarides (U.S. Patent No. 5,141,648), it would reside in optimizing the steps

of Hylarides (U.S. Patent No. 5,141,648). It would have been obvious to optimize the steps of Hylarides (U.S. Patent No. 5,141,648) to enhance separation.

Claims 81, 123, and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of either Schossler (U.S. Patent No. 4,822,681) or Carron (WO 98/59234) and Sohar (U.S. Patent No. 3,894,026). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in reciting use of a nitroso group and targeting a 1,3-diene group. Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups. Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group. Sohar (U.S. Patent No. 3,894,026) (column 4, lines 25-28 and 55-57) discloses thebaine, a compound containing a 1,3-diene group, is chromatographed to purify it. It would have been obvious to use a nitroso group and target a 1,3-diene group either because Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups or because Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61,

column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group and because Sohar (U.S. Patent No. 3,894,026) (column 4, lines 25-28 and 55-57) discloses thebaine, a compound containing a 1,3-diene group, is chromatographed to purify it.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hyalarides (U.S. Patent No. 5,141,648) in view of Stevens (U.S. Patent No. 4,927,539) and Schossler (U.S. Patent No. 4,822,681). At best, the claim differs from Hyalarides (U.S. Patent No. 5,141,648) in reciting use of a macroreticular polymer. Stevens (U.S. Patent No. 4,927,539) (column 2, lines 24-27) discloses that a macroporous polymer has higher capacity. Schossler (U.S. Patent No. 4,822,681) (column 8, line 40) discloses that reactive supports are conventionally macroporous. It would have been obvious to use a macroreticular polymer in Hyalarides (U.S. Patent No. 5,141,648) because Stevens (U.S. Patent No. 4,927,539) (column 2, lines 24-27) discloses that a macroporous polymer has higher capacity and because Schossler (U.S. Patent No. 4,822,681) (column 8, line 40) discloses that reactive supports are conventionally macroporous.

Claims 99, 101, and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyalarides (U.S. Patent No. 5,141,648) in view of either Carron (WO 98/59234) or Duran (WO 99/16907). At best, the claims differ from Hyalarides (U.S. Patent No. 5,141,648) in reciting use of a reactivity modifier group. Carron (WO 98/59234) (page 30, lines 9-30) discloses modifiers such as amines influence the reactivity between the reactive functional group and the analyte. Duran (WO 99/16907)

(page 6, lines 9-12 and page 7, lines 22-23) discloses ionic compounds such as amines attract target molecules. It would have been obvious to use a modifier in Hylarides (U.S. Patent No. 5,141,648) either because Carron (WO 98/59234) (page 30, lines 9-30) discloses modifiers such as amines influence the reactivity between the reactive functional group and the analyte or because Duran (WO 99/16907) (page 6, lines 9-12 and page 7, lines 22-23) discloses ionic compounds such as amines attract target molecules.

Claims 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of either Schossler (U.S. Patent No. 4,822,681) or Carron (WO 98/59234). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in reciting use of a nitroso group. Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups. Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group. It would have been obvious to use a nitroso group either because Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups or because Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60,

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lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group.

Claims 115, 116, and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in reciting use of methanol as an eluent. Kohn (U.S. Patent No. 6,362,008) (column 7, lines 59-62 and column 12, lines 16-25) discloses that use of methanol is a known releasing agent for covalent chromatography. It would have been obvious to use methanol in Hylarides (U.S. Patent No. 5,141,648) because Kohn (U.S. Patent No. 6,362,008) (column 7, lines 59-62 and column 12, lines 16-25) discloses that use of methanol is a known releasing agent for covalent chromatography.

Claims 79, 80, 87-91, 93-94, 106-107, 114-116, and 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in reciting use of methanol as an eluent. Kohn (U.S. Patent No. 6,362,008) (column 7, lines 59-62 and column 12, lines 16-25) discloses that use of methanol is a known releasing agent for covalent chromatography. It would have been obvious to use methanol in Hylarides (U.S. Patent No. 5,141,648) because Kohn (U.S. Patent No. 6,362,008) (column 7, lines 59-62 and column 12, lines 16-25) discloses that use of methanol is a known releasing agent for covalent chromatography.

Claims 81, 123, and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) as applied to claims 79, 80, 87-91, 93-94, 106-107, 114-116, and 121-122 above, and further in view of either Schossler (U.S. Patent No. 4,822,681) or Carron (WO 98/59234) and Sohar (U.S. Patent No. 3,894,026). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) in reciting use of a nitroso group and targeting a 1,3-diene group. Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups. Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group. Sohar (U.S. Patent No. 3,894,026) (column 4, lines 25-28 and 55-57) discloses thebaine, a compound containing a 1,3-diene group, is chromatographed to purify it. It would have been obvious to use a nitroso group and target a 1,3-diene group in Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) either because Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups or because Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a

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nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group and because Sohar (U.S. Patent No. 3,894,026) (column 4, lines 25-28 and 55-57) discloses thebaine, a compound containing a 1,3-diene group, is chromatographed to purify it.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) as applied to claims 79, 80, 87-91, 93-94, 106-107, 114-116, and 121-122 above, and further in view of Stevens (U.S. Patent No. 4,927,539) and Schossler (U.S. Patent No. 4,822,681). At best, the claim differs from Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) in reciting use of a macroreticular polymer. Stevens (U.S. Patent No. 4,927,539) (column 2, lines 24-27) discloses that a macroporous polymer has higher capacity. Schossler (U.S. Patent No. 4,822,681) (column 8, line 40) discloses that reactive supports are conventionally macroporous. It would have been obvious to use a macroreticular polymer in Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) because Stevens (U.S. Patent No. 4,927,539) (column 2, lines 24-27) discloses that a macroporous polymer has higher capacity and because Schossler (U.S. Patent No. 4,822,681) (column 8, line 40) discloses that reactive supports are conventionally macroporous.

Claims 99, 101, and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) as applied to claims 79, 80, 87-91, 93-94, 106-107, 114-116, and 121-

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122 above, and further in view of either Carron (WO 98/59234) or Duran (WO 99/16907). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) in reciting use of a reactivity modifier group. Carron (WO 98/59234) (page 30, lines 9-30) discloses modifiers such as amines influence the reactivity between the reactive functional group and the analyte. Duran (WO 99/16907) (page 6, lines 9-12 and page 7, lines 22-23) discloses ionic compounds such as amines attract target molecules. It would have been obvious to use a modifier in Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) either because Carron (WO 98/59234) (page 30, lines 9-30) discloses modifiers such as amines influence the reactivity between the reactive functional group and the analyte or because Duran (WO 99/16907) (page 6, lines 9-12 and page 7, lines 22-23) discloses ionic compounds such as amines attract target molecules.

Claims 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) as applied to claims 79, 80, 87-91, 93-94, 106-107, 114-116, and 121-122 above, and further in view of either Schossler (U.S. Patent No. 4,822,681) or Carron (WO 98/59234). At best, the claims differ from Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) in reciting use of a nitroso group. Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups. Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3)

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discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group. It would have been obvious to use a nitroso group in Hylarides (U.S. Patent No. 5,141,648) in view of Kohn (U.S. Patent No. 6,362,008) either because Schossler (U.S. Patent No. 4,822,681) (column 3, lines 3-22) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 amino, sulfhydryl, and carbonyl groups or because Carron (WO 98/59234) (page 27, lines 1-8 and page 59, line 30-page 60, lines 3) discloses that a nitroso group is interchangeable with Hylarides (U.S. Patent No. 5,141,648)'s column 9, lines 49-61, column 16, lines 19-59, column 32, lines 60-63 carbonyl groups as a reactive functional group.

The remarks urge that support can be found for "without the addition of a reagent acting at the covalent bond" in the specification's paragraph 48. However, paragraph 48 does not provide support for the phrase "acting at the covalent bond."

The remarks urge that support can be found for "without the addition of a reagent acting at the covalent bond" in paragraphs 38, 71, and 84-90 directed to use of an eluent. However, an eluent would appear by definition to be a reagent that removes the target molecule from the affinity molecule. This is particularly apparent in applicant's examples of using a pH modifying agent as an eluent. As such, no support can be found for "without the addition of a reagent acting at the covalent bond." Accordingly, the claims are considered to be directed to new matter.

The remarks urge patentability based upon the allegation that Hylarides (U.S. Patent No. 5,141,648) discloses washing. However, applicant's own specification discloses washing. Paragraphs 109 and 119's removal of interferents and impurities prior to removal of the target compound is considered to be washing. As such, washing is not considered to be excluded from the open format claims.

The remarks urge patentability based upon the allegation that Hylarides (U.S. Patent No. 5,141,648) does not disclose reversing the reaction "without the addition of a reagent acting at the covalent bond." However, Hylarides (U.S. Patent No. 5,141,648) on column 15, lines 46-58 discloses releasing the compound by use of a pH of 6 or lower and raising the temperature. This is the same technique that is recited in applicant's claims 119 and 120. As such, Hylarides (U.S. Patent No. 5,141,648) is considered to disclose reversing the reaction "without the addition of a reagent acting at the covalent bond."

The remarks urge patentability based upon the allegation that Hylarides (U.S. Patent No. 5,141,648)'s amino, sulfhydryl, and carbonyl groups are for binding his reactive compound to the solid phase material. However, a fair reading of Hylarides (U.S. Patent No. 5,141,648)'s column 16, lines 19-59 would indicate that reactive targeting group R' and the solid phase material binding group R may be the same groups.

The remarks appear to use that a nitroso group in Hylarides (U.S. Patent No. 5,141,648) would not be reversibly reactive. However, a nitroso group in Hylarides

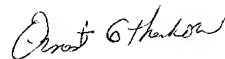
(U.S. Patent No. 5,141,648) would appear to be reversibly reactive for all same reason as it would be in applicant's claim 81.

The remarks urge that Kohn (U.S. Patent No. 6,362,008) is not pertinent because it discloses activated Sepharose. However, "activated" is a synonym for "reactive." As such, Kohn (U.S. Patent No. 6,362,008) is considered to be pertinent to reactive chromatography.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (703) 308-0362.



Ernest G. Therkorn
Primary Examiner
Art Unit 1723

EGT
November 18, 2003